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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,310	08/31/99	UKAI	K 425-736P

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EXAMINER	
HAGHIGHATIAN, M	
ART UNIT	**PAPER NUMBER**
1619	1

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/380,310	UKAI ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1619	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 21 are vague and indefinite due to "powders liquids".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matoba et al (5,464,612) in view of Aoki et al (JP407267850) and further in view of Balkin et al (5,656,284).

Matoba et al teaches that medicinally active ingredients having an unpleasant taste may frequently have a basic group. These basic medications such as basic antibiotics, tend to have a strong bitter taste, (see col. 4, lines 36-60). It is, therefore, a known fact that bad tasting medications need to be altered in order to increase patient compliance .

Matoba et al and Aoki et al, both teach the use of anionic (or water-soluble) polymers, such as carrageenan and sodium alginates as well as gums in taste masking

and as coating agents. They also have teachings on the type of medications that are good choices for taste masking. These classes of medications are: antibiotics, anti-depressives, antiallergics, etc, (see col. 4. Lines 1-30).

All three references cited, have teachings on the type of medications that are good choices for taste masking. These classes of medications are: antibiotics, anti depressives, antiallergics, etc, (see col. 4. Lines 1-30 of Matoba, and col. 6, lines 40-67 and col. 7, Lines 1-29 of Balkin).

Matoba teaches that generally basic medications have a bitter taste, and since donepezil hydrochloride is also a basic medication, it falls in the same class of medication in need of taste maskers.

The cephalosporine antibiotics are a class of medications of which, some contain basic groups. Cefpodoxime is one of these antibiotics that is named in teachings of Matoba and Balkin, thus meeting the limitations of the instant claims 5, 12 and 19.

Matoba teaches the amount of the ion exchanger used is about 10 to 5,000 parts by weight per 100 parts by weight of the active ingredient (see abstract).

The amount of polymer used as coating agent is a matter of effectiveness and economy. Matoba reads " the amount can be adequately selected from within the range not interfering with the dissolution property or releasability and absorbability of the active ingredient according to the type of the active ingredient". Matoba suggests a range of about 1 to 1,000 parts, but more preferably from about 7 to 30 parts (col. 6, lines 56-67).

Matoba and Aoki teach that the dosage form of said preparation may be, for example, powders, fine granules, granules, pills, syrups, etc, (see col. 5, lines 39-44 of Matoba and Aoki).

Matoba et al, Balkin et al and Aoki et al all teach the method of preparing the composition, which is very generic method and known to all in the art.

It would have been obvious to a person of ordinary skill in the art at the time of invention to have modified the basic medication containing bitter taste, of Matoba et al with the teachings of Aoki and Balkin on the type of polymers usefull in masking the unpleasent taste of these medicinal active ingredients, because of the expectation of making them more palatable for patients, specifically infants, children, elderly, or those with difficulty swallowing tablets and capsules. The basic medications having unpleasent taste, the polymers, the method of preparation and the amounts of polymer needed are all known in the art.

Response to Arguments

Applicant's arguments filed May 19th 2001 have been fully considered but they are not persuasive.

Applicant argues that Matoba teaches polymeric coating composition, which is used to coat a medicinally active ingredient contained within capsule shells such as microcapsules. However, Matoba clearly teaches that there are several approaches to masking bad taste of medicinally active ingredients, among them are the method comprising adding a corrigent such as a sweetener to a medicinally active ingredient

and processing the mixture into a preparation, or the method in which the medicinally active ingredient is absorbed physically on a carrier (col.1, lines 20-31).

Applicant argues that Matoba fails to encompass the claimed features of the present invention, which are directed to a basic medicine, which is blended with an anionic polymer. However, Matoba, even the teachings of coating, meets claims 1-7, because these claims do not exclude coating and are not specific to blending the ingredients. In addition Matoba, in column 3 reads "according to the method of the present invention, said powdery or granular preparation containing a medically active ingredient is **blended** with an ion exchanger to produce a solid preparation". It goes on to say that a method of masking a taste or odor of a medicinally active ingredient which comprises allowing a powdery or granular preparation containing a medicinally active ingredient having a taste or odor to be **co-existent** with a powdery or granular ion exchanger. Matoba in column 5, lines 35-44 discloses the dosage form of said preparations to include powders, fine granules, granules, etc.

Matoba discloses cation exchange resins and anion exchange resins can be used for medicinally active ingredient with unpleasent taste or odor (col.8, lines 5-11).

Applicant argues that Matoba does not teach combination of specific medications such as donepezil. This is correct, however as cited in the First Office Action, Matoba teaches that medications containing a basic group frequently have an unpleasant taste and/or odor. Donepezil and Cefpodoxime as claimed in claims 4, 5, 11, 12, 18 and 19, are medications containing base group(s) and therefore Matobe encompasses these limitations. Also in column 4, Matoba lists various medications with unpleasent taste, of

which cefpodoxime proxetil is named. In addition it is well known that Cefpodoxime is commercially available as powder for suspension, which contains polymers and flavoring agents.

Although Matoba meets all the limitations of the instant claims, Aoki et al and Balkin et al have added teachings on some of these limitations.

Conclusion

No claim is allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later tnan SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 703-308-6330. The examiner can normally be reached on MON-FRI from 9:30AM to 5:00PM. The fax phone numbers for the organization where this application or

proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.

Mina Haghighatian
Patent Examiner

DIANA DUDASH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

June 29, 2001